IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 2 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF NATHAN W. GOODYEAR, M.D.

Plaintiffs Tina and Kenneth Morrow are the only Wave 2 plaintiffs who have identified Nathan W. Goodyear, M.D. as their general-causation expert.[1] Although Dr. Goodyear did not submit a separate report setting forth his general-causation opinions, the Rule 26 specific-causation report he submitted for Plaintiff Tina Morrow contains several unsupported general-causation opinions that the Prolift and TVT-O products are defective in design and warnings. Dr. Goodyear's general-causation opinions should be excluded under this Court's own rulings, Rules 702 and 403, and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), because he is unqualified to render them, they are irrelevant, or they are the result of an unreliable methodology. These opinions include:

[1] Dr. Goodyear was deposed over two days in March 2016 and his testimony covered four different plaintiffs who had been his patients—Tina Morrow, Teri Shively, Charlene Taylor, and Dina Bennett. Although Plaintiff Tina Morrow is the only Wave 2 plaintiff who has identified Dr. Goodyear as her general-causation expert, Dr. Goodyear offered or explained some of his general-causation opinions in the deposition for Plaintiffs Shively and Taylor, which are referenced here where appropriate and attached as exhibits to the accompanying motion.

- **Opinion that safer alternative procedures exist.** An alternative surgical or nonsurgical procedure is not an alternative design that would support a design-defect opinion. This opinion is therefore irrelevant and inadmissible.

- **Opinion that the Prolift and TVT-O products cause various complications**. The only support Dr. Goodyear has for his complications opinions is his unscientific "recollection" of complications he claims he observed in his patient population; he collected no data nor has he conducted any analysis of his patient population to account for error rate and bias. Without more, his mere "recollection" is not a scientifically valid basis from which to formulate a reliable complications opinion.

- **Opinions that the mesh products are unreasonably dangerous.** These are inadmissible legal conclusions.

- **Opinion that the IFUs were inadequate because they did not contain severity-frequency or describe how to treat complications.** A medical-device manufacturer's duty runs to warning of risks of its products, not providing information it has no legal duty to provide.

- **Opinions about what Ethicon knew or should have known.** These opinions are inadmissible corporate-knowledge opinions.

As more fully explained below, Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) ask that these opinions be excluded.

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Goodyear is not qualified to give general-causation opinions.

Ethicon acknowledges that this Court has permitted certain urogynecologists and gynecologists to give opinions about mesh products. *E.g.*, *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 579-80 (S.D.W. Va. 2014). But those experts had a long and continued history of treating patients with pelvic organ prolapse and stress urinary incontinence, contributed to the medical literature, or otherwise engaged in research in the treatment of these conditions. *Id.*

Unlike those experts, Dr. Goodyear here practiced gynecological surgery for a total of nine years, from 2004 to 2013. Ex. B, Goodyear Report at 1. He decided "to make the whole move" from this field, stopped doing gynecological surgery altogether, and transitioned into "an office-based practice" that deals primarily with weight issues, menopausal-related issues, infertility, metabolic syndrome, hypertension, and diabetes. Ex. D, Goodyear 3/3/16 Dep. Tr. 56:5-12, 57:16-19, 58:3-7, 60:1. His focus now is on "metabolic medicine" or "anti-aging medicine"—which he claims is also known as "functional rejuvenative medicine"—where he is taking "traveling" and online courses to pursue a fellowship and advanced degree in this area. *Id.* at 108:23-109:14, 110:2-9; *see also id.* at 111:2-15.

He operates a Wellness Clinic where his focus is on patients—or clients as he calls them—who see him for his skills in nutrition, detoxification, aesthetics, preventative medicine, naturopathy, and holistic health, to name a few. *Id.* at 113:11-17, 121:9-20, 122:10-13, 122:19-24, 123:12-17. He conducts research in this area and has, in fact, published a reference book for physicians titled *Manboob Nation*, which discusses how excess weight in men correlates to increases in hormones that are responsible for breast growth. *Id.* at 50:18-52:3. Issues affecting wellness, weight, and nutrition have admittedly become his passion. *Id.* at 113:7-20. Gynecological surgery, including surgery using mesh products, is no longer a part of his practice and has not been for some time now because Dr. Goodyear cannot even recall the last time he performed any kind of surgery involving Prolift or TVT-O. *Id.* at 56:11-12, 58:18-59:23; Ex. C, Goodyear 3/4/16 Dep. Tr. 61:8-15.

While Dr. Goodyear, as a treating and implanting surgeon, can certainly testify as to his treatment of Ms. Morrow, he should not be able to give opinions about general causation for either product design or product warnings because he is too far removed from the practice of

gynecology and urogynecology to be considered an expert qualified to render general-causation opinions in this field. He is not practicing in this field any longer—and has not for some time—so that his opinions "grow[] naturally" from his present work. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995). In his words—he made a "whole move" (Ex. D, Goodyear 3/3/16 Dep. Tr. 60:1)—and should not be considered an expert in an area he no longer practices.

II. Dr. Goodyear's design-defect opinions are either irrelevant or based on an unreliable methodology.

A. Dr. Goodyear's safer-alternative opinion is irrelevant to a claim for design defect; an alternative procedure is not an alternative design.

Dr. Goodyear does not offer any opinions as to any alternative feasible *designs* for TVT-O or Prolift. He simply claims that safer surgical and nonsurgical alternative *procedures* exist, including "observation, the pessary, and then the non-mesh of the anterior/posterior colporrhaphy" as alternative procedures to Prolift; while pessaries, biofeedback, Kegel exercises, and vaginal cream are alternative procedures to the TVT sling. Ex. C, Goodyear 3/4/16 Dep. Tr. 175:13-15 (Prolift); *see also id.* at 175:18-21 (TVT); *see also* Ex. B, Goodyear Report at 7.

His opinions, however, are inadmissible because a medical device *product* is not defective in design simply because alternative surgical and nonsurgical *procedures* may exist. In *Talley v. Danek Med., Inc.*, 179 F.3d 154 (4th Cir. 1999), for example, the Fourth Circuit affirmed summary judgment for the defendant where the plaintiff's expert offered the same type of design-defect opinion as Dr. Goodyear offers here. The expert in *Talley* claimed that the defendant's spinal-fusion device was defective because there were more successful alternative spinal fusion procedures that did not use spinal-fixation devices. *Id.* at 162. The Court properly concluded, however, that the expert's opinion "did not indicate any design flaw," but rather "it questioned the medical judgment of doctors who use spinal fixation devices in surgery." *Id.*

Further, the Court reasoned that "[w]hile such an opinion might be relevant in a malpractice suit against a doctor, it is irrelevant in a suit against the product manufacturer." *Id.*

Courts around the country have similarly found surgical alternatives irrelevant to design-defect claims. *See, e.g.*, *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (granting summary judgment to defendant because "[t]he fact that an alternative method of surgical hernia repair was potentially available does not support[] Plaintiff'[s] design defect claim"); *Bogle v. Sofamor Danek Grp., Inc.*, No. 95–8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (emphasizing that the expert's "testimony fails to identify any particular defect *with the product*. He testified that the design of the screw made it difficult to utilize, that only the most skilled surgeons could implant it with any degree of success, that if he were designing a pedicle screw he would design it differently . . . The Court is not persuaded that such testimony identifies a defect in the product, rather, at the most it identifies that it is a product reserved to a top-rate surgeon") (emphasis added); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgment on design-defect claim where expert focused on surgical technique and noninstrumental spinal repair, not a defect in the product itself).

At bottom, alternative surgical *procedures*, including those using native tissue such as nonmesh colporrhaphy, are not alternative feasible *designs* that would support a design-defect claim. *See, e.g.*, *Linsley v. C.R. Bard, Inc.*, No. 98-2007, 2000 WL 343358, at *3 (E.D. La. Mar. 30, 2000) (granting summary judgment where expert had "merely show[n] that . . . there existed 'alternative techniques' for repairing a ventral hernia using Marlex Mesh, and not . . . an alternative design"); *Schmidt*, 2013 WL 3802804, at *2 ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support [a design defect] claim."); *Theriot v.*

Danek Med., Inc., 168 F.3d 253, 255-56 (5th Cir. 1999) (finding surgical alternatives that do not use pedicle screws cannot be considered "alternative designs"); *Toll v. Smith & Nephew Richards, Inc.*, No. 95-442, 1998 WL 398062, at *2 (E.D. La. July 14, 1998) ("Plaintiffs have only suggested alternative methods of [surgery] which utilize the System's already existing components; plaintiffs have not established an alternative design to the System. The component parts of the System remain the same.").

The same reasoning applies equally to nonsurgical treatment procedures because "alternative methods of treatment are not alternative designs." *Hornbeck v. Danek Med., Inc.*, No. 99-30966, 2000 WL 1028981, at *1 (5th Cir. July 5, 2000), 226 F.3d 641 (Table) (applying Louisiana law, which applies here and requires evidence that an alternative design exists; summary judgment granted because the plaintiff claimed only that "alternative methods of treatment should have been used" and, as the court concluded, "alternative methods of treatment are not alternative designs").

Dr. Goodyear's safer-alternative opinion should be excluded in its entirety. An alternative method of treatment—whether surgical or nonsurgical—is not an alternative design that can support Plaintiffs' design-defect claims. Dr. Goodyear's safer-alternative opinion is therefore irrelevant and inadmissible under *Daubert*.

B. Dr. Goodyear's opinions that mesh causes various complications that Ethicon "underreported" are unsupported and speculative.

In his report, Dr. Goodyear offers a laundry list of complications for both the Prolift and TVT-O. Ex. B, Goodyear Report at 6-7. The only "support" he provides in his report is that these complications "have been reported in peer-reviewed medical literature, and have been observed by me in my own practice." *Id.*

1. Dr. Goodyear's opinions as to what he observed in his own practice are unsupported and speculative.

Dr. Goodyear admitted it is "hard to say" how many of the 300 Ethicon procedures he performed resulted in complications. Ex. D, Goodyear 3/3/16 Dep. Tr. 129:5-8. He conducted no analysis of any kind of the complications he claims he observed in his patient population.

> Q. Did you keep track of these complications, talking about the erosion right now?
>
> A. I told the rep about them.
>
> Q. But did you internally -- do you have any kind of documentation or objective data that would verify that?
>
> A. That's what the medical charts are for.
>
> Q. Right. Aside from your medical charts, do you have any compilation of the data where you've had a 15 to 20 percent erosion rate beginning in the 2006 time period?
>
> A. I didn't do an IRB-approved study, no.
>
> Q. Even outside of an IRB, do you just have some data that you collected?
>
> A. No . . .

Id. at 130:3-17. Dr. Goodyear's off-the-top-of-his-head "recollection" of the percentage of his patients that experienced erosions is wholly without support and is nothing more than pure speculation.

Even if Dr. Goodyear had provided some objective data supporting the erosion rate he claims he observed in his patient population, there is nothing to show that he accounted for the potential rate of error, which is a foundational hallmark of the scientific method. *Daubert*, 509 U.S. at 594; *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 687-88, 701 (S.D.W. Va. 2014) ("I have previously rejected testimony . . . that arbitrarily states a complication rate without explaining the method of doing so."). An expert's "best recollection," which is all really

Dr. Goodyear is relying upon here, is not sufficient. *Id*. at 679; *see also Tyree*, 54 F. Supp. 3d at 525. Dr. Goodyear's "memory" simply provides no reliable basis for him to render complications or complications-rate opinions. *Eghnayem*, 57 F. Supp. 3d at 701. On the contrary, his opinions must "be connected to existing data by something more than [his] 'it is so because I say it is so'" opinion. *Holesapple v. Barrett*, 5 F. App'x 177, 180 (4th Cir. 2001).

Dr. Goodyear fails to make that connection here. His memory and best recollection are not reliable bases from which he can offer opinions that he observed certain complications in his practice in general and that his erosion rate in particular was 15 to 20 percent. He should be prohibited from offering those opinions here.

2. Dr. Goodyear's opinion that Ethicon "underreported" erosion rates is unsupported and speculative.

In deposition, Dr. Goodyear repeatedly criticized Ethicon for "underreporting" the erosion rate. Ex. D, Goodyear 3/3/16 Dep. Tr. 94:6-97:12, 99:9-100:4. He claimed he was told by unidentified Ethicon representatives that the erosion rate he relayed to his patients—three to five percent—"were the numbers that the -- Ethicon told me to put." *Id.* at 163:14-15. He admittedly identified no Ethicon literature that supported that particular erosion rate, nor could he identify any Ethicon representatives who reportedly made those representations. Ex. C, Goodyear 3/4/16 Dep. Tr. 45:5-17. Again, it is his "recollection" that it was someone affiliated with Ethicon and somewhere in the 2008 timeframe who gave him this information. *Id*. at 43:22-45:17; 46:21-48:15; 57:8-12. And it was this three to five percent erosion rate that he relayed to his patients, despite reportedly observing, albeit based on "memory," a 15 to 20 percent erosion rate in his own practice. Ex. D, Goodyear 3/3/16 Dep. Tr. 156:14-159:12.

Dr. Goodyear's "underreporting" opinion should be excluded for two reasons. First, it is wholly unsupported and based on pure speculation. He can identify no Ethicon document that

provided this information. Indeed, Dr. Goodyear had to admit that the Clinical Study Report—*Evaluation of the TVM technique for treatment of genital prolapse*—he claimed was his support says no such thing. Ex. E, Goodyear 3/3/16 Dep. Tr. 68:21-70:2; *see also* Ex. F, Clinical Study Report. He ultimately admitted he has no such documentation.

> Q. And where do you have any documentation where Ethicon is telling you to put three to five erosion risk?
>
> A. I don't have it.
>
> Q. Okay. So you have no evidence, correct?
>
> . . .
>
> THE WITNESS: No.

Ex. D, Goodyear 3/3/16/ Dep. Tr. 163:16-22.

In fact, Dr. Goodyear conceded that Ethicon's Prolift Surgeon's Resource Monograph plainly states that "simple vaginal mesh exposure . . . occurs in approximately three to 17 percent of cases." *Id.* at 162:9-24, 163:24-164:4; *see also* Ex. G, *Gynecare Prolift Surgeon's Resource Monograph* at 8. His response was that this is "a wide range" and that the three to five percent he quoted nonetheless "falls within the three to 17 percent" range. Ex. D, Goodyear 3/3/16/ Dep. Tr. 166:20-167:3; Ex. E, Goodyear 3/3/16 Dep. Tr. 72:22-23. Merely because the three to 17 percent range is "wide" and the considerably narrower range he quoted falls within that range does not mean that the Surgeon's Resource Monograph supports his underreporting opinion. Dr. Goodyear's "underreporting" opinion simply has no support and should be excluded.

III. Dr. Goodyear's warnings opinions are based on an unreliable methodology, are irrelevant, or are inadmissible legal conclusions or corporate-knowledge opinions.

A. Dr. Goodyear's opinion that the IFUs are inadequate because they do not include severity, frequency, and responsiveness information is unsupported and a legal conclusion.

Dr. Goodyear will testify that the IFUs were inadequate because they did not include "severity, frequency and responsiveness to treatment" information. Ex. B, Goodyear Report at 8. He provides no support for this opinion. *Id.* Without any scientific support that this information should be included in the IFUs, Dr. Goodyear's opinion that the IFUs are inadequate without this information is a legal conclusion within the province of the jury and should be excluded. *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *5 n.4. (S.D.W. Va. Feb. 7, 2015). This Court has also excluded this type of opinion testimony for lack of reliability where the expert can point to no support—and Dr. Goodyear provides none here—showing that a manufacturer should include frequency-severity information in its IFU. *See Frankum v. Boston Scientific Corp.*, No. 2:12-cv-00904, 2015 WL 1976952, at *21 (S.D.W. Va. May 1, 2015) (excluding warnings opinion that frequency-severity information should be included in the manufacturer's IFU where there was no support that this information should be included). It should be excluded here as well.

B. Dr. Goodyear's opinions that the IFUs are inadequate because they do not inform the physician how to treat the complications is contrary to law and irrelevant.

Courts consistently exclude expert testimony that is contrary to law because it is neither probative nor relevant, noting that this testimony cannot assist the jury in making factual determinations and also creates the potential for confusion. *See Martinez v. Porta*, 601 F. Supp. 2d 865, 866 (N.D. Tex. 2009) ("[A]n [expert's] opinion cannot be based on an erroneous legal premise."); *Whitney Nat'l Bank v. Air Ambulance by B & C Flight Mgmt., Inc.*, 516 F. Supp. 2d

802, 816 (S.D. Tex. 2007) (excluding experts' testimony that "assumes a legal duty that the record does not support"); *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2010 WL 4259332, at *7 (S.D. Fla. Oct. 21, 2010) (excluding expert testimony because it "likely will be contrary to law"); *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 1796334, at *30–31 (N.D. Ohio May 4, 2010) (precluding expert witness from offering interpretation of federal regulations that contradicts a Supreme Court decision).

Despite this well-established rule of law, Dr. Goodyear claims the IFUs are inadequate because they do not "describe how physicians are to treat patients who experience complications," nor do they "describe the invasive nature of surgical procedures necessary to treat [the] complications." Ex. B, Goodyear Report at 8. Like his frequency-severity opinion, Dr. Goodyear provides no support for this opinion. But even more importantly, there is no duty on the part of a device manufacturer to inform a duly licensed physician how to practice medicine. Instead, the duty of a pharmaceutical manufacturer generally is to warn the prescribing physician of the risks of its *product*. *See Rhoto v. Ribando*, 504 So. 2d 1119, 1123 (La. Ct. App. 1987) (applying Louisiana law applicable here). Recognizing a duty to inform of treatment for complications would turn each IFU into a long surgical manual requiring discussion of multiple treatment options. On the contrary, the duty of a medical-device manufacturer is to set forth the risks of its product—not provide a diatribe of treatment options.

Moreover, the information that must be included in a medical-device IFU is circumscribed by the FDA. *See* 21 C.F.R. § 801.109. The regulation does not require the manufacturer to describe how physicians are to treat their patients who may experience complications. This regulation interacts with and is an exception to 21 U.S.C. § 352(f)(1) providing a prescription device is misbranded unless its labeling bears "adequate directions for

use." *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1348 (10th Cir. 2015) (Lucero, J., dissenting); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284-85 (11th Cir. 2002). An expert witness should not be permitted to offer testimony about what an IFU should contain where it is inconceivable that the FDA would have permitted it.

C. Dr. Goodyear's opinions that the Prolift and TVT-O are unreasonably dangerous are inadmissible legal conclusions.

This Court has made clear on numerous occasions that drawing legal conclusions is within the province of the jury, not the subject of expert testimony. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013); *see also Eghnayem*, 57 F. Supp. 3d at 691.

Despite this well-established rule of law, Dr. Goodyear opines that the Prolift and TVT-O are "unreasonably dangerous" and their IFUs were false, misleading, and inadequate. Ex. B, Goodyear Report at 8, 10. Consistent with the Court's earlier rulings, Dr. Goodyear should be precluded from offering these legal conclusions.

D. Warnings opinions based on what Ethicon knew or should have known are not helpful to the jury and should be excluded.

Dr. Goodyear will testify that Ethicon "knew or should have known" of various complications and should have advised "clinicians and patients" of the complications and the "medical treatment required to treat these complications." Ex. B, Goodyear Report at 7. This opinion should be excluded for three reasons. First, the duty to warn runs to the physician, not the patient under Louisiana law applicable here. *Rhoto*, 504 So. 2d at 1123. Second, as discussed, Ethicon has no duty to advise a licensed physician how to practice medicine; instead its duty runs to warning of the risks of its products. *Id.*

Lastly, this Court has repeatedly held that it will not permit expert testimony on "Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics" because these matters "are not appropriate subjects of expert testimony because opinions on

these matters will not assist the jury." *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D.W. Va. Jan. 15, 2014); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D.W. Va. 2014); *In re C.R. Bard*, 948 F. Supp. 2d at 611, 629. Instead, the jury is capable of drawing its own conclusions of what Ethicon knew or should have known without expert testimony. *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004).

CONCLUSION

For these reasons, Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Nathan W. Goodyear, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 21, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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